Summary of Safety and Effectiveness

JAN 28 2011

Date: April 28, 2010

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Manufacturer:
Lima-Lto S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

Product	Product Code	Regulation and Classification Name
SMR Uncemented Shoulder System	KWT	Shoulder joint metal/polymer non-constrained cemented prosthesis per 21 CFR 888.3650
	HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.3690

Device Description:

The SMR Shoulder System consists of a humeral stem, a humeral body, an adaptor taper, a humeral head and a glenoid component. Components are offered for hemi or total shoulder joint arthroplasty, in primary trauma surgery. Humeral components are provided in different designs and are intended for cemented or cementless use while glenoid components are intended for cemented use only.

Two designs of humeral stems are available: the first one (object of this submission) is intended for uncemented use while the second one (submitted in 510(k): K100858) is intended for cemented use only.
Two lengths of uncemented humeral stems are available: 60 and 80 mm. The 60 mm stems are characterized by an outline with a double conicity and they are finned to provide optimal proximal fixation. The stem is sand-blasted. The 80 mm stems are characterized by an outline with a triple conicity and are also finned to provide optimal proximal fixation. The proximal part is sand-blasted while the distal part is polished. All stems are made from Ti6Al4V (ISO 5832-3, ASTM F1472). The stems are provided with a male Morse taper (identical to that described in K100858) to allow coupling with the humeral bodies.

Humeral bodies are available in two designs. The first one (submitted in 510(k): K100858) is characterized by holes for humeral bone reconstruction as a consequence of trauma while the second one (object of this 510(k)) is finned to allow proximal press-fit fixation of the humeral system. Both designs of humeral bodies can be used in cemented (with cemented stems submitted in 510(k): K100858) and in uncemented applications (with uncemented stems submitted in this 510(k). Humeral bodies are made from Ti6Al4V (ISO 5832-3, ASTM F1472).

They are coupled with the humeral stem via a female Morse-taper connection; a locking screw is provided to aid in initial mating of the stem / body assembly.. Cylindrical marks are designed at the base of this Morse-taper to provide correct alignment of the eccentricity of the humeral head during surgery. A male Morse-taper connection is designed for the coupling between the humeral body and the humeral head by means of specific adaptor tapers: an angle of 45° between the axis of this Morse-taper and the axis of the stem gives the correct varus-valgus alignment to the joint.

The device descriptions for the adaptor tapers, humeral heads and glenoid components submitted in K100858 are repeated here in italic typing for a better understanding of the complete system.

Adaptor tapers (neutral and eccentrical with different heights), are made from Ti6Al4V. They allow coupling between the humeral body and the humeral head. These devices are designed to adjust the centre of rotation of the joint and provide the required offset to the humeral head to achieve the correct tensioning to the soft tissues, optimizing joint stability.

The humeral heads are made from CoCrMo (ISO 5832-12, ASTM F1537). They are intended to articulate with the glenoid bone in hemi-arthroplasty or with the glenoid component in total shoulder arthroplasty. The surface is polished to aid in the reduction of wear.

The glenoid components are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE ISO 5834-2, ASTM F648). The articulating surface has a radius of curvature greater than the corresponding humeral head, which allows translation in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has a single central peg which is inserted in the hole drilled in the glenoid cavity during surgery. The peg surface has three grooves to provide enhanced cement fixation.

Intended Use / Indications:

The SMR Shoulder system is intended for partial or total primary shoulder joint replacement. The components are intended for use in cemented and uncemented applications, as specified in the following table:

COMPONENT	USE	
	Cemented	Uncemented
Cemented stems	X	
Cementless Finned stems		X
Trauma Humeral Bodies	X	X
Finned Humeral Bodies	X	X
Humeral Heads	X	X
Adaptor Tapers	X	X
Cemented Glenoids	X	

Total or hemi-shoulder replacement is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods

Predicate Devices:

- Promos modular shoulder system (PlusOrthopedics, K032126, K063578);
- Anatomical shoulder system (Centerpulse, K030259);
- Modular Shoulder System (Acumed, K992525)

Comparable Features to Predicate Device(s):

The SMR Shoulder System is similar to the predicate devices in terms of intended use, indications, design and materials. The SMR Shoulder System and the predicates are all intended for partial or total primary shoulder joint replacement. The SMR humeral stems,are intended for cemented or uncemented use, depending on the design, as are the predicate humeral stems. The indications of all of the systems are similar with the exception that the SMR Shoulder System is not indicated for revision procedures.

Like the Promos Modular and Acumed Modular Shoulder Systems, the SMR Shoulder System provides modular humeral stem and humeral body components. The Anatomical Shoulder System is designed as a one-piece humeral stem / body component. The SMR Shoulder System and the Promos Modular Shoulder System include modular adaptor tapers for adjustment of the humeral head. The Anatomical Shoulder System and the Acumed Modular Shoulder System do not include adaptor tapers.

The components of the SMR Shoulder System are manufactured from the same or similar materials as the predicate devices. The SMR, Promos and Acumed humeral stems are manufactured from Ti6Al4V while the Anatomical cemented humeral stems are manufactured from cast CoCrMo.

Non-Clinical Testing: The SMR Shoulder System has undergone static pull-out and/or torsional testing of all modular connections; fatigue testing to demonstrate both the strength of the humeral stem and the post-fatigue strength of the modular connections; static shear and torsional testing of the glenoid component; and fatigue testing of the glenoid component. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the SMR Shoulder System to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JAN 28 2011

Re: K101263
Trade/Device Name: SMR Uncemented Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: January 10, 2011
Received: January 19, 2011

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

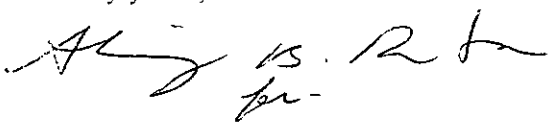
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101263

p. 1/1

510(k) Number (if known): Unknown
Device Name: SMR Uncemented Shoulder System
Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mckeown

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101263